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FITZPATRICK CELLA HARPER & SCINTO			EXAMINER	
30 ROCKEFELLER PLAZA			ELLIS, SUEZU Y	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,031	<b>Applicant(s)</b> MALCOLM ET AL.
	<b>Examiner</b> Suezu Ellis	<b>Art Unit</b> 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 July 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 January 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/1648)           | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

**FINAL REJECTION**

***Response to Arguments***

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Objections***

Claim 15 is objected to because of the following informalities:

With respect to claim 15, the different pore-forming excipients should be separated with a comma instead of semi-colon for consistency. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Zaffroni (US 3,993,072).

With respect to claim 1, Zaffroni discloses in Examples 1,16 and 18, an intravaginal drug delivery device (intrauterine device) for administration into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent (progesterone) or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer (polydimethylsiloxane), and a porous sheath surrounding the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment. Since the sheath has pores, it is considered to discontinuously surround the reservoir.

With respect to claim 13, Zaffroni discloses in Example 18, the device is a ring (toroid shape).

With respect to claim 17, Zaffroni discloses the intravaginal device can be made by forming a reservoir by dispersing at least one pharmacologically active agent in a pharmaceutically acceptable hydrophobic elastomer polymer, curing the reservoir, and applying a sheath to partly surround the reservoir. (col. 20, lines 28-37).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-8, 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes (US 3,977,404) in view of Zaffroni.

With respect to claim 1, Theeuwes discloses in Fig. 6, an intravaginal drug delivery device (intrauterine device) for administration into a vaginal environment, the device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent (anti-fertility agent) or a prodrug thereof, dispersed therein, and a sheath (12) discontinuously surrounding the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment (col. 6, lines 6-11). Theeuwes further discloses the reservoir can be made of a hydrophobic polymer (col. 9, lines 20-21), however fails to expressly disclose the hydrophobic polymer being elastomeric. Zaffroni teaches an intrauterine device having a reservoir comprising progesterone (anti-fertility agent) dispersed in a polydimethylsiloxane (hydrophobic elastomeric polymer) (Examples 1, 16 and 18). It would have been obvious to one of ordinary skill in the art to modify the material of the reservoir in order to provide the desired solubility of the pharmacologically active agent of the desired pharmacologically active agent used (col. 6, lines 12-22). Further, it has

been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

With respect to claims 2 and 3, the modified Theeuwes illustrates in Fig. 6, the at least one hole or opening extending through the sheath to the at least one reservoir, so that at least part of the at least one reservoir is exposed, in use, to the vaginal environment.

With respect to claim 6, the modified Theeuwes illustrates in Fig. 6, the at least one hole or opening extends through the sheath substantially normal to the reservoir surface.

With respect to claims 7, 8 and 13, the modified Theeuwes discloses the intrauterine device has an opening that communicates with the exterior of the device (col. 6, lines 6-11), and further discloses the shape of the vaginal/cervical device can be in the shape of Ota's ring. Therefore, the at least one hole or opening in the sheath would extend substantially radially, through the sheath at the inner or outer circumference of the ring.

With respect to claims 14 and 15, the modified Theeuwes discloses the reservoir comprises at least one pore-forming excipient (solvent) (col. 8, line 50 - col. 9, line 2; col. 15, lines 5-7).

With respect to claim 17, the modified Theeuwes discloses the intravaginal device can be made by forming a reservoir by dispersing at least one pharmacologically active agent in a pharmaceutically acceptable polymer, curing the reservoir, and applying a sheath to partly surround the reservoir. (col. 15, lines 17-25). The modified Theeuwes further discloses the reservoir can be made of a hydrophobic polymer (col. 9, lines 20-21), however fails to expressly disclose the hydrophobic polymer being elastomeric. Zaffroni teaches an intrauterine device having a reservoir comprising progesterone (anti-fertility agent) dispersed in a polydimethylsiloxane (hydrophobic elastomeric polymer) (Examples 1, 16 and 18). It would have been obvious to one of ordinary skill in the art to modify the material of the polymer in order to provide the desired solubility of the pharmacologically active agent of the desired pharmacologically

active agent used (col. 6, lines 12-22). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Zaffroni and further in view of Brooke (US 3,924,622).

With respect to claim 4, the modified Theeuwes illustrates in Fig. 6, a hole or opening, however fails to expressly disclose the at least one hole or opening is in a shape of a slit. Brooke discloses an intravaginal device having a slit (Figs. 1 and 3). Brooke further teaches that the shape of the hole or opening in a drug delivery device affects the release rate of the drug (abstract; col.3, lines 7-11). It would have been an obvious design choice to modify the shape of the hole or opening in order to attain the desired release rate of the pharmacologically active agent. Further, a change in shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Claims 5, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Zaffroni and further in view of Chappaz et al. (US 2,962,023).

With respect to claim 5, the modified Theeuwes addresses all the limitations of claims 1 and 2, however fails to expressly disclose the exact shape and size of the at least one hole or opening. Chappaz et al. discloses a medicator for use in the vaginal cavity having a plurality of holes with a diameter in the size in the range of about 0.5-6.5 mm (col. 1, lines 36-45; col. 4, lines 5-8). Chappaz et al. further discloses the hole is circular, therefore are considered to be substantially cylindrical since they inherently have a depth. It would have been obvious to one of ordinary skill in the art to modify the size of the at least one hole or opening in order to attain the desired release rate of the pharmacologically active agent, as taught by Chappaz et al. (col. 1, lines 36-43).

With respect to claims 9, 11 and 12, the modified Theeuwes addresses all the limitations of claims 1 and 2, and further discloses the device can be cylindrical (col. 6,

lines 28-31), however fails to expressly disclose at least one hole or opening is provided at each terminal end of the rod. Chappaz et al. discloses in Fig. 2, a device for use in the vaginal cavity in the shape of cylindrical rod having at least one hole or opening at each of the terminal ends and additional holes or openings provided extending substantially radially through the sheath. It would have been obvious to one of ordinary skill in the art to modify the shape of the device, as desired, in order to attain complete insertion within the vaginal cavity with optimum comfort, and to include at least one hole or opening at each terminal end and additional holes or openings extending substantially radially through the sheath in order to deliver the desired pharmacologically active agent along the entire device to cover more surface area of the vaginal cavity wall for medication, as taught by Chappaz et al. (col. 1, lines 32-35; col. 3, lines 19-23). Further, a change in shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Zaffroni and further in view of Chappaz et al. and further in view of Heller et al. (US 4,014,987).

With respect to claim 10, the modified Theeuwes addresses all the limitations of claims 1, 2 and 9, and further discloses the device can be cylindrical (col. 6, lines 28-31), however fails to expressly disclose the rod device defines a right circular cylinder and each base of the rod is partly or fully exposed, to define the holes. Chappaz et al. discloses in Fig. 2, a device for use in the vaginal cavity in the shape of cylindrical rod having at least one hole or opening at each of the terminal ends. However Chappaz et al. also fails to expressly disclose the rod is a right circular cylinder. Heller et al. discloses in Fig. 8, a device for administering drug into the cervical canal having a right circular cylinder shape, as well as a plurality of perforations in its walls (col. 15, lines 24-28). It would have been obvious to one of ordinary skill in the art to modify the shape of the device, as desired, in order to attain complete insertion within the cervical canal with optimum comfort, and to partly or fully expose each base of the rod to define the holes

in order to allow passage of cervical fluid through the device. Further, a change in shape is generally recognized as being within the level of one of ordinary skill in the art.  
*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Zaffroni and further in view of Shaw, Jr. (US 4,359,046).

With respect to claim 16, the modified Theeuwes addresses all the limitations of claim 1, however fails to expressly disclose the sheath comprises at least one additional pharmacologically active agent. Shaw, Jr. teaches it is known in the art for intrauterine devices to have a coating (sheath) comprising a different drug than the drug within the body of the device (col. 13, lines 28-32). It would have been obvious to one of ordinary skill in the art to incorporate at least one additional pharmacologically active agent within the sheath in order to provide a desired release rate of a combination of drugs, as desired for the predictable result of achieving effectiveness (col. 13, lines 12-17).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Zaffroni and further in view of McKenna et al. (US 6,394,094).

With respect to claim 18, the modified Theeuwes addresses all the limitations of claim 1, however fails to expressly disclose the intravaginal drug delivery device is made via injecting or extruding a reservoir material into a hollow sheath. McKenna et al. discloses it is known in the art to manufacture an intravaginal drug delivery device by injecting or extruding a reservoir material into a hollow sheath (col. 6, lines 42-46; col. 8, lines 26-29). It would have been obvious to one of ordinary skill in the art to make the intravaginal drug delivery device by injecting or extruding a reservoir material into a hollow sheath in order to attain a substantially uniform thickness of the sheath (col. 8, lines 37-39).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffroni in view of McKenna et al. (US 6,394,094).

With respect to claim 18, Zaffroni addresses all the limitations of claim 1, however fails to expressly disclose the intravaginal drug delivery device is made via injecting or extruding a reservoir material into a hollow sheath. McKenna et al. discloses it is known in the art to manufacture an intravaginal drug delivery device by injecting or extruding a reservoir material into a hollow sheath (col. 6, lines 42-46; col. 8, lines 26-29). It would have been obvious to one of ordinary skill in the art to make the intravaginal drug delivery device by injecting or extruding a reservoir material into a hollow sheath in order to attain a substantially uniform thickness of the sheath (col. 8, lines 37-39).

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone/Fax Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615